REMARKS

Claims 1-29, 34-36 and 51 are presently pending in the application.

The Office Action rejected claims 1, 2, 4, 5, 14-17, 21, 22, 34-36 and 51 under 35 U.S.C. 102(b) as allegedly being anticipated by Arm et al. (WO 93/20859). The Office Action also rejected claims 1, 4, 7-18, 21 and 22 under 35 U.S.C. 103(a) as allegedly being unpatentable in view of Hossainy et al. (Patent 6,451,373, published 9/17/02), rejected claims 1, 4, 7, 13-23, 25, 29 and 34-36 under 35 U.S.C. 103(a) as allegedly being unpatentable over Lahtinen et al. (Publication 2003/0059463, published 3/27/03), rejected claims 1, 3, 4, 5, 21-28 and 51 under 35 U.S.C. 103(a) as allegedly being unpatentable over Ledergerber (Patent 4,955,907, published 9/11/1990) in view of Schneider (Patent 3,636,956, published 1/25/1972), and further rejected claim 6 under 35 U.S.C. 103(a) as allegedly being unpatentable over Ledergerber in view of Schneider and further in view of Vijayan et al (Patent 5,047,054, published 09/10/91). Applicants respectfully traverse these rejections, for the following reasons.

I. 102(b) Rejection of Claim 1 Using Arm et al. Improper Since No Disclosure of "Non-Porous" Membrane

Regarding the claimed "nonporous" film characteristic of claim 1, page 3 of the Office Action states that Arm et al. is "silent to this," but Applicants disagree, and direct the Examiner's attention to page 11 of the Arm et al. disclosure which indicates the carriers of that invention as being capable of creating pores in the film. That same page also states that the Arm et al. films are designed to promote tissue growth or infiltration, which language clearly denotes a requirement of pores. In contrast, the current claim 1 of Applicants is directed to, among other things, membranes that are substantially non-porous. Thus, the nonporous structure of claim 1 and those dependent therefrom are not anticipated.

II. 102(b) Rejection of Claim 1 Using Arm et al. Improper Since No Disclosure of Claimed Implant Material

Applicants would like to direct the Examiner's attention to various passages in Applicants' specification which emphasize an aspect of the current invention in which the membranes comprise a layer of polymer base material selected from the group consisting essentially of a lactide polymer and a copolymer of two or more cyclic esters. Applicants' Background of the Invention section, for example, states that "[o]ne approach to the problem of adhesion has been the use of bioresorbable barrier materials, in the form of … coatings, … films, and the like, that are placed between a healing post-surgical site and adjacent surrounding tissue." Clearly, Applicants' presently claimed invention is not directed to such a broad concept as any and all bioresorbable coatings on implants.

Applicants' Background of the Invention section, furthermore, references several prior-art disclosures which are characterized as disclosing methods for coating implants to address the problem of foreign body reactions. Such prior-art devices are distinguished from the currently claimed invention, as a result of, among other things, the prior-art devices taking too long to resorb, being insufficiently malleable, or requiring complex chemical formulations and/or reactions which may increase the cost of manufacturing.

The second paragraph in Applicants' Summary of the Invention section describes membranes according to an aspect of the current invention as scar tissue-reduction barrier membranes which are constructed entirely of resorbable polymers, and selected from the group consisting of lactide polymers (e.g., copolymers) of two or more lactides. Applicants submit that reducing tissue growth (i.e., scars or adhesions) is disclosed throughout Applicants' application as a primary objective of the invention.

Concerning the Office Action's contention that page 3, line 36 and 37, and page 4, lines 1-8, of Arm et al. teach a film of 100% polylactic acid (wherein the addition of a carrier and peptide growth factor to that film is allegedly disclosed as just a preferred embodiment, and not required), Applicants must respectfully disagree. Regarding the reasoning for Applicants' disagreement, page 3, lines 33-35 of Arm et al. initially describe "sustained release compositions for the therapeutic delivery of polypeptide growth factors," and, then, the next lines 36 and 37 follow-up

by further describing "[t]he compositions" (emphasis added) as being biodegradable. That is, those lines 36 and 37 are not describing just any compositions, or compositions in general, but, rather, are specifically referring back to and further describing "the" compositions that were just discussed in the preceding lines 33-35. Now, the compositions of the Arm et al. invention are described in those lines 36 and 37 as being "for the therapeutic delivery of polypeptide growth factors." Of course, as mentioned, in order to deliver the growth factors, the films of Arm et al. would appear, in the context of that invention, to need to contain the growth factors. The following page 4, lines 1-8 of Arm et al. describes the film of that invention as containing, at least, a copolymer, one or more polypeptide growth factors, and a carrier.

Furthermore, in connection with the Office Action's statement that Arm et al. discloses 100% polylactic acid film," Applicants respond that this construction is not regarded by that disclosure as useful and, to the contrary, is characterized on more than one occasion in the in Arm et al. disclosure, that construction is discredited and dismissed as a "sham" (emphasis added, cf. page 18, line 32 and page 19, line 17).

Being limited to "compositions … in the form of biodegradable polyester films …, one or more peptide growth factors, and a carrier" (emphasis added), the Arm et al. reference actually teaches away from use of a 100% polylactic acid film coating on an implant, because, according to Arm et al., such structure will not work. Moreover, to the extent one of the growth-factor films of Arm et al. were to be provided on an implant (e.g., a screw), that film would actually work to encourage tissue growth, rather than to impede it. Regarding page 4 of the Office Action and the allegation that "Arm et al. do in fact … disclose … 100% polylactic acid film," Applicants request that the Examiner point out, for example, where such film is disclosed as being non-porous and disposed over more than just "only one side" of the implant. Since such identifications, among others, cannot be made, Claim 1 and those dependent therefrom thus are not anticipated.

III. Restriction Requirement Already Deemed Claims As "Patentably Distinct" Over Hossainy et al.

Page 3 of a Restriction Requirement mailed September 6, 2006 split-up the originally-filed claims into "patentably distinct" species and required Applicants to elect "a single disclosed species … to which the claims shall be restricted" (emphasis added). In particular, the Applicants were required to elect "a single disclosed implant such as heart valves and a single disclosed surrounding tissue such as pericardium."

In response to the Restriction Requirement's instruction that the Applicants must elect "a single species for prosecution on the merits" (emphasis added), the Applicants elected for examination the species of artificial organs surrounded by soft tissues.

Following Applicants' election, the Office Action proceeded to search and uncover Hossainy et al., which is directed to a non-elected species, namely, "stents and grafts" surrounded by "vessel walls." The Applicants did not elect "stents and grafts." Nor did the Applicants elect "vessel walls." Accordingly, since the relied-upon prior art in the Office Action is directed to a non-elected species, rather than "artificial organs surrounded by soft tissuesApplicants request that all rejections based upon that prior art be withdrawn as being directed to a non-elected species.

IV. Section 2111.03[R-3] of MPEP Does Not Apply in View of Applicants' Clear Indication of Invention Over Asserted And Synergistic Features

The Office Action cited to Section 2111.03[R-3] of the MPEP for a con-patent proposition, allegedly that, "absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising.'" More particularly, on page 8 of the Office Action, the Examiner in his rejection appeared to challenge the Applicants to show that the Hossainy et al. "carrier [and] compound such as actinomycin would materially affect the basic or novel characteristic of the instantly claimed invention."

A. General Considerations

Initially, with regard to general anti-scarring barrier considerations of the present invention, Applicants direct the Examiner's attention to Provisional Application 60/196,869, filed Mar. 10, 2000, the last page of which is attached hereto as Exhibit A. (The current application incorporates by reference Provisional Application 60/409,137, which incorporates by reference Application 09/805,411, which incorporates by reference Provisional Application 60/196,869.) That last page summarizes a number of anti-scarring tests that were performed on a number of materials and constructions, with the currently claimed one appearing to outperform the others.

In connection with this data, Applicants' Background describes how prior-art coatings and other barriers have met with limited success. For instance, as also discussed in Provisional Application 60/196,869, Applicants' Background describes how some of the prior-art barrier materials may be resorbed into the body too quickly, yielding undesirable drops in local pH levels, which may cause or exacerbate such problems as local inflammation, discomfort and/or foreign antibody responses. Other materials may take too long to resorb, may be insufficiently malleable, or may require complex chemical formulations and/or reactions which can increase the cost of manufacturing. Furthermore, the Detailed Description of the current application describes, in the text referencing Fig. 1, a method of applying a non-porous film formed of a single layer of polylactide material to maintain a smooth-faced barrier between an implant and surrounding tissues. Such features of the present invention, including, among others, resorption time, smoothness, and non-porosity, are synergistic, and were not arbitrarily thrown together from a laundry list of attributes or features. The unique combinations include the provision of a simple-to-make (e.g., from simple compositions/reactions; cf. Pub. US07/0116739, par. 0007 and 0008) anti-adhesive membrane that offers reduction in both chemical tissue inflammation (e.g., the membrane is ultra-thin, for less inflammation during resorption; cf. Pub. US07/0116739, par. 0051) and mechanical tissue inflammation (e.g., non-leaking barrier, smooth, non-porous, cf. Pub. US07/0116739, par. 0047 and 0050; yet strong enough to have value and versatility; cf. par. 0031 and 0032, 0043). Pre-implantation stretching at glass transition temperatures (i.e., biasing) facilitates shrink-wrapping of the fragile, ultra-thin membranes (c.f. Pub. US07/0116739, par. 0035 and 0036), in an advantageous and novel fashion, around implants. For instance, when

positioned around an implant and brought to its glass transition temperature, the present membrane returns, under its own memory, to its pre-biased or pre-stretched configuration, thereby contracting around and, optimally, smoothly enveloping (for less tissue turbulence), the implant.

B. Particular Considerations

Furthermore, with regard to particular anti-scarring barrier considerations raised by the Examiner, such as on page 8 of the outstanding Office Action, Applicants' submit that a carrier and an actinomycin compound, such as allegedly taught by Hossainy et al., would materially affect the basic or novel characteristic of the instantly claimed invention. As exemplified on the last page of Provisional Application 60/196,869, and in various other places including, for example, the first paragraph of the Summary of the current application, a purpose of the implants of the presently claimed invention is to prevent undesired reactions between the implant and surrounding tissues. This purpose would not be met with the relatively reactionary and toxic actinomycin compound of Hossainy et al. The Examiner's attention is directed to Exhibits 1-4, attached hereto, for information on the Hossainy et al. actinomycin compound. Accordingly, Applicants' "consisting essentially of" claim language should be construed true to its intended, non-skewed meaning, and the rejection based upon Hossainy et al. should be withdrawn.

V. 103(a) Rejection of Claim 1 Using Lahtinen Improper Since No Disclosure of Non-Porous Claimed Implant Material

On the rejection based upon Lahtinen, the Examiner provided, as a motivation to combine, a statement that "[o]ne would have been motivated to use polylactic acid as the polymer base coating for vascular graft because Lahtinen makes polylactic acid a preferred embodiment for coating a vascular graft. (See paragraph 135)." Applicants respectfully disagree. To the contrary, while paragraph 135 of Lahtinen does, indeed, mention polylactic acid and polyglycolic acid, it states that such materials may be used to "deliver the gene composition and also provide a surface for new endothelium growth…[acting as] scaffold[s] through which endothelial cells [may] migrate." (Emphasis added, to indicate composition and porous structure.) Accordingly, Lahtinen does not appear to disclose or suggest membranes which (1) comprise a layer of polymer base

material selected from the group consisting essentially of a lactide polymer and a copolymer of two or more cyclic esters and which (2) are substantially non-porous. The Examiner in the rejection continued, stating that "if one desired to utilize a vasculature coated graft, a skilled artisan would utilize a polylactic acid polymer base coating suggested by Latinen." However, even assuming, arguendo, that such a statement could have merit, such a coating would not lead one skilled in the art to Applicants' claimed invention. The Examiner in the rejection based upon Lahtinen further stated that "one would also be motivated to form a nonporous polymer film because Lehtinen teaches [in paragraph 130] that a nonporous film 'serves to provide tear resistance.'" However, the very next sentence in that paragraph 130 requires that those allegedly "nonporous" nodal regions be connected "with the spaces … [to provide] the porosity referred to herein" (emphasis added). In any event, it is respectfully submitted that the reference's disclosed function of providing a surface acting as a scaffold through which endothelial cells [may] migrate for new endothelium growth would be more important than preventing tearing, so that one skilled in the art would not interpret paragraph 135 of Lahtinen as encompassing nonporous polylactic acid films. The Examiner's citation, again, to and reliance on Section 2111.03[R-3] of the MPEP is, this time, so vague as not to be comprehensible. Further details are thus requested so that Applicants may have an opportunity fairly in which to respond. Based upon the above and other reasons, the outstanding rejection under 35 U.S.C. § 102(e) of claim 1, and claims dependent therefrom, is improper.

VI. 103(a) Rejection of Claim 14 Using Ledergerber/Schneider Improper Since No Teaching of Non-Porous Claimed Implant Material

In this rejection, the Office Action characterizes the claimed invention as being directed to, among other things, "a method for attenuating adhesion between an implant (i.e. organ) and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide surrounding an implant" and then cites column 6, lines 57-62 of Ledergerber for disclosing "any material which promotes limited tissue ingrowth" (emphasis added; cf. page 14 of Office Action). That same paragraph of Ledergerber defines promoting limited tissue ingrowth as embodying "a high degree of ultramicroporosity which invites tissue

ingrowth" and comprising "approximately 50% air by volume." The next paragraph of that reference describes the implant as comprising a "stretch weave in the form of a blind sock to permit complete envelopment of the implant" to be "held around the implant 10 by means of a drawstring," such structure hardly equating to the currently claimed "non-porous" structure.

As for Schneider, it discloses a polylactide polymer filament, but that is all. As for the quotation on page 14 of the Office Action that the Schneider polymers can be "cast into films," those three words are taken out of context. The actual language containing the three words says that "it is possible to … cast it into films, which are then ... cut into narrow strips for use as sutures." Accordingly, the Schneider's filaments appear to be cumulative of the prior art already discussed in Applicants' Background section of the current application, such as in connection with Tang et al. Moreover, there does not appear to be any motivation to combine the Ledergerber tissue-ingrowth socks with the Schneider suture filaments, and, even if there were, any conceivable combination would be nonsensical and certainly would not yield Applicants' combinations of claimed elements.

The Office Action's statement that "one would have been motivated to do so because Ledergerber teaches that any material that impedes tissue in-growth … can be used as a covering" is clearly misleading since, as established above, Ledergerber teaches using "material[s] which promote … tissue ingrowth" (emphasis added), rather than impede it.

The Office Action gives, as another motivation-to-combine, the isolated, conclusive statement that "[o]ne would further be motivated to use the film sheet of Schneider [with Ledergerber's tissue ingrowth implant] because the film taught by Schneider is bioabsorbable." First, in the context of this rejection, what does "bioabsorbable" have to do with anything, as the Office Action appears to give no relevance or nexus between this feature and Ledergerber's implants. Does Ledergerber mention somewhere a need or desire for bioabsorbable implants? Secondly, it was already established above that Schneider does not even disclose "films" but rather films cut-up into strips to form sutures. Indeed, it seems that the implants allegedly taught by Schneider do not appear to be directed to promoting tissue ingrowth (which, for compatibility, is the focus of Ledergerber), do not appear to be directed to covering implants (which may be a focus of Ledergerber), and furthermore, to the extent biosorbable, do not appear to bear any nexus to the

Ledergerber implants by operation of that (bioabsorbable) feature, so that, in summary, the only common thread connecting these two references would appear to be the Office Action's hindsight. Thus, the outstanding rejection under 35 U.S.C. § 103(a) is improper.

VII. 103(a) Rejection of Claim 6 Using Ledergerber/Schneider/Vijayan et al. Improper Since No Teaching of Claimed Heat Shrinking of Non-Porous Claimed Implant Material

The discussion of Part VI, above, is incorporated herein. In particular, since Ledergerber and Schneider are not combinable absent "hindsight" gleaned from the present application, the rejection of claim 6 based upon yet another reference, would appear to be even more nonsensical. Furthermore, as discussed in Part VI, even if, hypothetically, combinable, Ledergerber and Schneider would not come close to yielding, or suggesting, any of the currently claimed combinations.

It is well established that a claim can be rejected on obviousness grounds only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior-art reference or combination of prior-art references. Thus, for a rejection under 35 U.S.C. 103(a) to be proper, every limitation recited in a claim, which is rejected as being obvious in view of a combination of prior-art references, must be disclosed or taught in that collection of prior-art references. In the instant case, Applicants respectfully submit that the collection of all three of the cited references neither disclose nor suggest each and every element that is recited in the rejected claims. For example, not a single one of the references discloses the claim limitation of, for example, a "method ... attenuating adhesions between [a] implant and the surrounding tissues" (emphasis added), of claim 6 and its base claim 1. That is, Ledergerber is an adhesion promoting implant, Schneider is a fiber (having a shape hardly capable of the claimed attenuating of adhesions), and Vijayan is an adhesion promoting implant (see Vijayan: col. 3, lines 56, 4/55,56; col. 5, lines 21-26; col. 6, lines 12,13,40-48,54-58; col. 7, lines 37-43).

Furthermore, not a single one of the references discloses the same claim limitation of a "method ... attenuating adhesions" that is further characterized by "essentially ... a lactide polymer; or a copolymer of two or more cyclic esters" (emphasis added), of claim 6 and its base claim. This combination of limitations clearly is neither taught nor suggested by Ledergerber and

Schneider, taken separately or together, in any combination, and, furthermore, is most certainly neither taught nor suggested by Vijayan, taken alone or in combination with any one or more of Ledergerber and Schneider. The adhesion promoting implants of Vijayan are limited to compositions consisting of resins, along with various combinations of plasticizers and other non-claimed agents (see Vijayan: col. 3, lines 15,16,19,20, 39; col. 5, lines 21-26,46-52,61,62; col. 6, lines 12,13,40-48, 54-58; col. 7, lines 37-43), none of which in any way disclose or suggest the combinations of limitations such as recited in claim 6. Accordingly, since several of the individual limitations are nowhere present in single one or more of any of the relied-upon references, no matter how those references are combined, the missing limitations still will not be, and are not, present in any hypothetical combination of the relied-upon references.

Moreover, in addition to there being no motivation to combine the Ledergerber tissue-ingrowth implants with the Schneider suture filaments, there certainly would have been no motivation to add-in Vijayan's resin-based chemicals and agents into the Office Action's creative, hindsight-based creation. On the motivation-to-combine issue, the Office Action seemingly was a conservationalist on logic. The "motivation to combine" was asserted in the current 103(a) rejection as being, simply, "because heating the coating ... would provide for a tightly adherent coating." Heating which coating? Where is there any evidence or suggestion stating that the porous, non-resin "sock" of Ledergerber or the "thread" of Schneider would benefit from "a tightly adherent coating"?

Clearly, the Office Action has not provided an adequate articulation to how the three relied-upon, quite divergent references could have been viewed as combineable by one skilled in the art. While the Office Action states that one would have been motivated to combine the references "because heating the coating ... would provide for a tightly adherent coating," this makes no sense since, for instance, Vijayan uses heat to cure a resin, but Ledergerber and Schneider do not appear to seek heating as they do not even appear to use resins.

In more detail, it should be contextualized that the allegedly "heat-benefiting" implant of Ledergerber is a weaved sock with a drawstring closure, and the proffered "heat-benefiting" implant of Schneider is nothing more than a filament. Since neither of the Ledergerber and Schneider implants are resin-based in need of heat curing, no motivation, whatsoever, has been

provided for combining the porous, resin-based implant teachings of Vijayanwith with the porous, non-resin "socks" and "threads" of Ledergerber and Schneider. Applicants request that the Examiner kindly answer, without referencing or "borrowing from" Applicants' disclosed pre-loading membrane forming techniques (cf. twelfth paragraph of Detailed Description), how one skilled in the art would have derived any motivation to "heat" his or her membrane, and, furthermore, how a person skilled in the art would be led or, perhaps more precisely, misled, into believing that "heating" the porous, non-resin "sock" or "thread" of Ledergerber or Schneider would cause either to shrink. Also, why would either reference seek shrinkage? It is submitted that a skilled artesian would not expect heating of the Ledergerber sock or the Schneider thread to cause shrinkage, and/or advantageous shrinkage, and would be correct.

Even still, to the extent hypothetically performed, such heating of such implants, as discussed above, would not serve to "tighten" them, as asserted by the Office Action. The evidence appears to indicate that, on the motivation-to-combine issue, any combination of the Ledergerber tissue-ingrowth socks, the Schneider filaments, and the Vijayan resins, would not have been indicated, or sensible, and, to the extent hypothetically integratable, any conceivable such combination would be nonsensical or at best impracticable, and certainly would not have yielded Applicants' combinations of elements such as recited, for example, in claim 6. Accordingly, the outstanding rejection under 35 U.S.C. § 103(a) of claim 6 is improper and should be withdrawn.

With respect to the claims not specifically mentioned above, it is submitted that each of these claims is likewise free and clear of the scope of the cited references to similar and even greater degrees, not only by virtue of its dependency upon the respective base claim but also for the totality of features recited therein

In view of these and potentially other reasons, Applicants disagree with the Examiner's position that the instantly claimed method of attenuating adhesions between an implant and surrounding tissues is anticipated or would have been obvious.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 102 and 103. Applicants submit that the application is now in condition for allowance, and an early indication of same is requested. The Examiner is invited to contact the undersigned with any questions.

The Commissioner is hereby authorized to charge any needed fees to deposit account 50-1600.

Respectfully submitted,

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Registration 36,331

April 14, 2008

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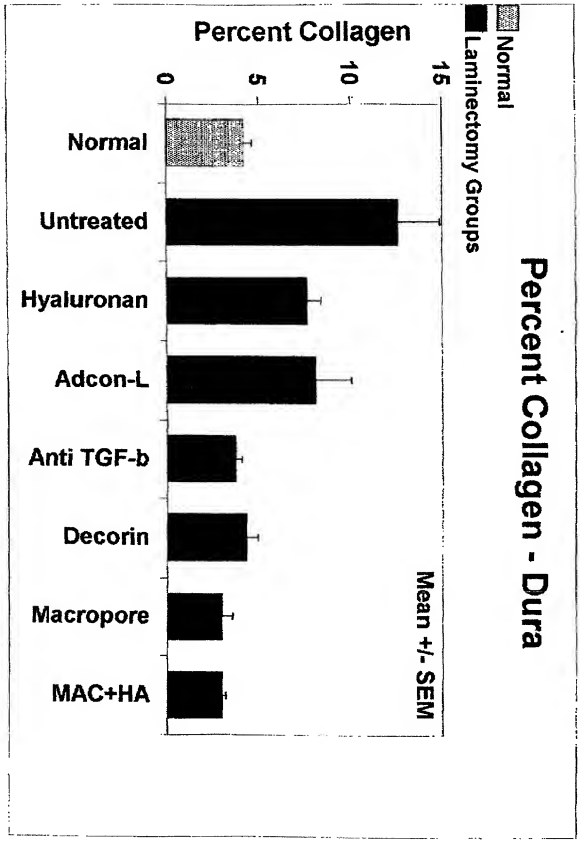
Percent Collagen - Dura
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Laminectomy Groups
Percent Collagen
0
5
10
15
Normal
Untreated
Hyaluronan
Adcon-L
Anti TGF-b
Decorin
Macropore
MAC+HA
Mean +/- SEM
N=3
N=3

Safety data for actinomycin D

Glossary of terms on this data sheet.

The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers.

General

Synonyms: dilactone actinomycin D acid, ACT, actinomycin A IV, actinomycin CL, AD, cosmegen, dactinomycin, meractinomycin, oncostatin K
Use: antineoplastic agent
Molecular formula: $C_{62}H_{86}N_{12}O_{16}$
CAS No: 50-76-0
EINECS No:

Physical data

Appearance: red crystalline powder
Melting point: ca. 240 C (decomposes)
Boiling point:
Vapour density:
Vapour pressure:
Density (g cm^{-3}):
Flash point:
Explosion limits:
Autoignition temperature:
Water solubility:

Stability

Stable, but light sensitive, especially in dilute solution. Incompatible with strong acids, strong bases, strong oxidizing agents. Combustible.

Toxicology

Poison. Toxic if swallowed or inhaled, or if absorbed through the skin. Skin irritant. Experimental teratogen, carcinogen.

Toxicity data

(The meaning of any toxicological abbreviations which appear in this section is given here.)

ORL-MUS LD50 13 mg kg^{-1}

Risk phrases

(The meaning of any risk phrases which appear in this section is given here.)

R23 R24 R25 R38.

Transport information

(The meaning of any UN hazard codes which appear in this section is given here.)

UN No 2811. Hazard class 6.1. Packing group I.

Personal protection

Safety glasses, gloves, adequate ventilation.

Safety phrases

(The meaning of any safety phrases which appear in this section is given here.)

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The Columbia Encyclopedia, Sixth Edition. 2001-07.

actinomycin

(ăk´´tənōmī´sən) (KEY) , any one of a group of antibiotics produced by bacteria of the genus *Streptomyces*. Actinomycin was the first antibiotic reported to be able to halt cancer; however, it is not widely used to treat cancers because it is highly toxic to humans, interfering with the genetic material of cells. It is mainly used as an investigative tool in cell biology.

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EXHIBIT D

Actinomycin D (Dactinomycin) 2nd edition Information for children and families

Contents

Introduction
What is actinomycin?
How is it given?
What are the most common side effects?
What are the less common side effects?
Important information you should know

This leaflet should be read in conjunction with any patient information leaflet provided by the manufacturer.

Introduction

This fact sheet explains what actinomycin D (dactinomycin) is, how it is given and some of the possible side effects. Some rare and long term side effects are explained as well as the more common ones. Each person reacts differently to drugs so your child will not necessarily suffer every side effect mentioned. If you are concerned about any of these side effects, please ring one of the contact numbers on this factsheet and ask for your doctor, nurse or pharmacist.

What is actinomycin?

Actinomycin D is a chemotherapy drug which is used to treat certain types of cancer.

How is it given?

It is given as an injection into a vein (intravenously or IV) through a cannula, central venous catheter, implantable port or PICC line.

What are the most common side effects?

Nausea and vomiting:
Anti-sickness drugs can be given to reduce or prevent these symptoms. Please tell your doctor or nurse if your child's sickness is not controlled or persists.

Mouth sores and ulcers:
You will be given advice about appropriate mouth care including a copy of the mouthcare leaflet. If your child complains about having a sore mouth please tell your doctor or nurse.

Bone marrow suppression:
There will be a temporary reduction in how well your child's bone marrow works. This means that he or she may become anaemic, bruise or bleed more easily than usual, and have a higher risk of infection. Your child's blood count will be checked regularly to see how the bone marrow is working. Please tell your doctor if your child seems unusually tired, has bruising or bleeding or any signs of infection, especially a high temperature.

Hair loss:
Your child may lose all their hair or it may become thinner. This is temporary and the hair will grow back once the treatment has finished.

What are the less common side effects?

Diarrhoea or stomach pain:
Please tell your doctor or nurse if your child has diarrhoea or stomach pain which is not controlled or

Download

Download our leaflet: Actinomycin D (Dactinomycin) (PDF, 198KB)

Links

children first for health
Health and hospital information for children and young people

choose and book
NHS 'Choose and Book' service for GP referral

Referring an international or private patient

Feedback

NHS CALL 24 HOURS 0845 Direct 4647

persists. It is important that your child drinks lots of fluids.

Inflammatory skin reaction:
Sometimes actinomycin D may cause your child's skin to become red and sore in the areas which have recently been treated with radiotherapy.

Changes in liver function:
Actinomycin D may change how well your child's liver works. These changes may happen rapidly. Blood tests will be taken to monitor your child's liver function during treatment (LFTs). Please discuss this with your doctor.

Important information you should know

If actinomycin D leaks into the tissues underneath your child's skin, it can damage the tissue in this area. If this drug is given through a cannula, and your child complains of stinging and burning around the cannula, please tell your doctor or nurse immediately. If this drug is given through acentral venous catheter or implantable port and your child complains of pain around their chest or neck, please tell your doctor or nurse immediately.

Useful Numbers

Elephant Day Care 020 7829 8833
Fox Ward 020 7829 8820
Giraffe Ward 020 7829 8821
Lion Ward 020 7829 8810
Robin Ward 020 7829 8811

UCL Institute of Child Health
30 Guilford Street, London WC1N 1EH
Tel. +44 (0)20 7242 9789. Fax. +44 (0)20 7831 0488
Link to UCL website

Great Ormond Street Hospital for Children NHS Trust
Great Ormond Street, London WC1N 3JH
Tel. +44 (0)20 7405 9200. Fax: +44 (0)20 7829 8643

Dactinomycin

(dak ti noe mye' sin)

Printer-friendly version | E-mail to a friend

Contents of this page:

- About your treatment
- Other uses for this medicine
- Precautions
- Side effects
- In case of emergency/overdose
- Special instructions
- Brand names

IMPORTANT WARNING: Return to top

Dactinomycin when administered into a vein may leak into surrounding tissue. Your doctor or nurse will monitor your administration site for this reaction.

About your treatment Return to top

Your doctor has ordered the drug dactinomycin to help treat your illness. The drug is given by injection into a vein.

This medication is used to treat:

- Wilms' tumor
- rhabdomyosarcoma
- Ewing's sarcoma
- trophoblastic neoplasms
- testicular carcinoma

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

Dactinomycin is a type of antibiotic that is only used in cancer chemotherapy. It slows or stops the growth of cancer cells in your body. The length of treatment depends on the types of drugs you are taking, how well your body responds to them, and the type of cancer you have.

Other uses for this medicine Return to top

Dactinomycin is also used to treat various sarcomas, carcinomas, and adenocarcinomas. It has also been used to treat Kaposi's sarcoma; to manage acute organ rejection in patients with kidney or heart transplants; in the treatment of malignant melanoma, acute lymphocytic leukemia, and advanced tumors of the breast and ovary; and in the treatment of Paget's disease. Talk to your doctor about the possible risks of using this drug for your condition.

Precautions Return to top

Before taking dactinomycin,

- tell your doctor and pharmacist if you are allergic to dactinomycin or any other drugs.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially aspirin and vitamins.
- tell your doctor if you have or have ever had liver disease, ulcers, or gastrointestinal disease.
- you should know that dactinomycin may interfere with the normal menstrual cycle (period) in women and may stop sperm production in men. However, you should not assume that you cannot get pregnant or that you cannot get someone else pregnant. Women who are pregnant or breast-feeding should tell their doctors before they begin taking this drug. You should not plan to have children while receiving chemotherapy or for a while after treatments. (Talk to your doctor for further details.) Use a reliable method of birth control to prevent pregnancy. Dactinomycin may harm the fetus.
- do not have any vaccinations (e.g., measles or flu shots) without talking to your doctor.

Side effects Return to top

Side effects from dactinomycin are common and include:

- nausea and vomiting which may last up to 24 hours after treatment
- loss of appetite
- abdominal pain
- diarrhea
- difficulty swallowing
- thinned or brittle hair
- blistering skin or acne
- skin irritation (sunburn-like) or rash on areas previously exposed to radiation treatments

Tell your doctor if either of these symptoms is severe or lasts for several hours:

- fatigue
- mouth blistering

If you experience any of the following symptoms, call your doctor immediately:

- unusual bruising or bleeding
- pain at the injection site
- persistent diarrhea or any change in normal bowel habits for more than 2 days
- fever
- chills
- cough
- sore throat
- dizziness
- shortness of breath
- yellowing of the skin or eyes

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at http://www.fda.gov/MedWatch/index.html] or by phone [1-800-332-1088].

In case of emergency/overdose Return to top

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Special instructions Return to top

- The most common side effect of dactinomyin is a decrease of blood cells. Your doctor may order tests before, during, and after your treatment to see if your blood cells are affected by the drug.

Brand names

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- Cosmegen®

Last Revised - 04/01/2003
Last Reviewed - 08/01/2007

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